

**Amendments to the Drawings:**

The sheets of drawings attached to this paper include replacement sheets for Figs. 5, 13a, and 13b and annotated sheets showing changes to these Figures.

Per the Examiner's request, reference number 204 has been deleted from Fig. 5 and reference numbers 500 and 502 have been deleted from Figs. 13a and 13b, respectively. In addition, some of the lead lines of Figs. 13a and 13b have been amended to place Figs. 13a and 13b in conformance with the specification. No new matter has been added.

### **REMARKS**

The Examiner's comments in the Office Action mailed December 21, 2006 have been carefully considered. Claims 10-14, 16-20, 23, and 39-50 have been canceled without prejudice or disclaimer as drawn to the non-elected species. Applicants reserve the right to pursue claims 10-14, 16-20, 23, and 39-50 in a later filed continuing application. Claim 1 has been amended to clarify the configuration of the sheath. Editorial revisions have been made to claims 5, 7, and 38 to correct antecedent basis and grammatical issues. Support for the amendments can be found throughout the specification and figures of the application, e.g., in Fig. 10. No new matter has been added.

Reconsideration of the application is requested in view of the above amendments and the following remarks.

### **Election of Claims**

Applicants have elected to pursue claims 1-9, 15, 21, 22, and 24-38. Claims 10-14, 16-20, 23, and 39-50 have been canceled without prejudice or disclaimer as being drawn to the non-elected species. Applicants reserve the right to pursue the subject matter of claims 10-14, 16-20, 23, and 39-50 in a continuing application.

### **Information Disclosure Statement**

Applicants respectfully submit herewith a Supplemental Information Disclosure Statement and Form 1449 to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609.

The Office Action noted typographical errors on two previously submitted Forms 1449. To correct these errors, the Form 1449 submitted herewith includes U.S. Patent No. 5,449,343 to Samson et al. and U.S. Publication No. 2003/0130716 to Weber et al. The '343 patent had been listed on the Form 1449 submitted March 18, 2004 as U.S. Patent No. 5,449,353 to Samson et al. The '716 publication had been listed on the Form 1449 submitted August 31, 2004 as U.S. Publication No. 2003/01300716 to Weber et al.

Applicants respectfully request consideration of the references submitted with this Form 1449.

### **Objections to the Drawings**

Formal objections were made to the drawings for including reference numbers not mentioned in the specification. The Examiner's comments have been considered and appropriate correction has been made. In particular, reference number 204 has been deleted from Fig. 5 and reference numbers 500 and 502 have been deleted from Figs. 13a and 13b, respectively. In addition, some of the lead lines of Figs. 13a and 13b have been amended to place Figs. 13a and 13b in conformance with the specification. No new matter has been added.

Applicants assert the objection is overcome. Withdrawal of the objection is respectfully requested.

### **35 U.S.C. § 112**

Claim 32 has been rejected for failing to comply with the requirements of 35 U.S.C. §112, second paragraph. Applicants respectfully traverse the rejection.

Applicants assert the term "tecophilic" in claim 32 is not being used as a trademark to indicate a source of goods. Rather, the term "tecophilic," as written in lowercase letters and used in claim 32, was defined on page 8, lines 12-15 of the present application as indicating materials that provide a sheath with rotatability in a "dry", or pre-insertion, state, but with the application of a greater amount of force than when in the wet state.

Applicants assert the rejection is overcome and request withdrawal of the rejection. Applicants do not otherwise concede the correctness of the rejection and reserve the right to make additional arguments if necessary. If the Examiner disagrees with the non-trademark use of the term "tecophilic," then the Examiner is requested to call Applicants' attorney at the telephone number listed below to discuss the issue.

### **35 U.S.C. § 102**

Claims 1, 5-6, 15, 33, 35, and 37-38 are rejected under 35 U.S.C. §102(b) as being anticipated by Stone et al. (U.S. Patent No. 5,843,027). Applicants respectfully traverse the rejection.

Claim 1 recites, in part, a rotatable sheath including a first portion arranged axially adjacent a second portion.

In contrast, Stone fails to disclose or suggest a sheath having a first portion arranged axially adjacent a second portion. Rather, Stone discloses a sheath having a first portion being coaxial with a second portion.

No motivation is provided in Stone or any of the cited references to modify the sheath of Stone to move the first portion to a position axially adjacent the second portion. In fact, arranging the sheath portions in this manner would destroy the functionality of the sheath in Stone. The inner portion of the sheath in Stone constrains a balloon to a relatively noncompliant inflation profile and the outer portion reduces the risk of perforation of the sheath and the balloon.

For at least these reasons, Stone does not anticipate or suggest claim 1. Claims 5, 6, 15, 33, 37, and 38 depend from claim 1 and are allowable for at least the same reasons. Withdrawal of the rejection and allowance of claims 1, 5, 6, 15, 33, 37, and 38 is respectfully requested. Applicants do not otherwise concede the correctness of the rejection and reserve the right to make additional arguments if necessary.

### **35 U.S.C. § 103**

Claims 2-4 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone as applied to claim 1, and further in view of Wilson et al. (U.S. Patent No. 6,165,195). Applicants respectfully traverse the rejection.

Applicants assert the combination of Stone and Wilson does not disclose or suggest all of the elements of claims 2-4. Claims 2-4 depend from claim 1 and are allowable over Stone for at least the same reasons as discussed above with respect to claim 1. Wilson does not overcome the shortcomings of Stone. Wilson also does not disclose or suggest a rotatable sheath including a first portion arranged axially adjacent a second portion.

For at least these reasons, Stone would not lead a person having skill in the art to the invention of claims 2-4, even in view of Wilson. Withdrawal of the rejection and allowance of

claims 2-4 is respectfully requested. Applicants do not otherwise concede the correctness of the rejection and reserve the right to make additional arguments if necessary.

Claims 7-9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone as applied to claim 6, and further in view of Bigus et al. (U.S. Patent Publication No. 2002/0052640). Applicants respectfully traverse the rejection.

Applicants assert the combination of Stone and Bigus does not disclose or suggest all of the elements of claims 7-9. Claims 7-9 depend, indirectly, from claim 1, which further recites the first portion of the rotatable sheath being arranged in radial alignment with a first portion of a balloon and the second portion of the rotatable sheath being arranged in radial alignment with a second portion of the balloon that has a different outer diameter than the first portion of the balloon.

Neither Stone nor Bigus discloses such an arrangement of a rotatable sheath and a balloon. Rather, Stone merely discloses two coaxial sheath portions arranged over the same balloon. Bigus does not overcome the shortcomings of Stone. Bigus does not disclose or suggest a balloon including portions having different outer diameters. Rather, Bigus discloses providing variations in sheath thickness to control where the sheath will fail (i.e., break). See e.g., Bigus, column 7, lines 5-8. Moreover, no motivation is provided in Bigus to so modify the balloon.

For at least these reasons, Stone would not lead a person having skill in the art to the invention of claims 7-9, even in view of Bigus. Withdrawal of the rejection and allowance of claims 7-9 is respectfully requested. Applicants do not otherwise concede the correctness of the rejection and reserve the right to make additional arguments if necessary.

Claims 21-23 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone as applied to claim 15, and further in view of Bigus. Applicants respectfully traverse the rejection.

Claims 21-23 depend, indirectly, from claim 1 and are allowable over the combination of Stone and Bigus for at least the same reasons as discussed above with respect to claims 7-9. For at least these reasons, Stone would not lead a person having skill in the art to the invention of

claims 21-23, even in view of Bigus. Withdrawal of the rejection and allowance of claims 21-23 is respectfully requested. Applicants do not otherwise concede the correctness of the rejection and reserve the right to make additional arguments if necessary.

Claims 24-26, and 29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone as applied to claim 15, and further in view of Healy et al. (U.S. Patent No. 5,670,161). Applicants respectfully traverse the rejection.

Applicants assert the combination of Stone and Healy does not disclose every feature of claims 24-26, and 29. Claims 24-26, and 29 depend from claim 1 and are allowable over Stone for at least the same reasons as discussed above with respect to claim 1. Healy does not overcome the shortcomings of Stone. Healy also fails to disclose or suggest a rotatable sheath including a first portion arranged axially adjacent a second portion. Rather, Healy is directed to a biodegradable stent.

For at least these reasons, Stone would not lead a person having skill in the art to the invention of claims 24-26, and 29, even in view of Healy. Withdrawal of the rejection and allowance of claims 24-26, and 29 is respectfully requested. Applicants do not otherwise concede the correctness of the rejection and reserve the right to make additional arguments if necessary.

Claims 27 and 28 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone in view of Healy as applied to claim 24 above, and further in view of Clapper (U.S. Patent No. 5,744,515). Applicants respectfully traverse the rejection.

Applicants assert the combination of Stone, Healy, and Clapper does not disclose every feature of claims 27 and 28. Claims 27 and 28 depend from claim 24 and are allowable over the combination of Stone and Healy for at least the same reasons as discussed above with respect to claims 24-26, and 29. Clapper does not overcome the shortcomings of Stone and Healy. Rather, Clapper is directed to promoting endothelialization with implantable devices.

For at least these reasons, Stone would not lead a person having skill in the art to the invention of claims 27 and 28, even in view of Healy and Clapper. Withdrawal of the rejection and allowance of claims 27 and 28 is respectfully requested. Applicants do not otherwise

concede the correctness of the rejection and reserve the right to make additional arguments if necessary.

Claim 30 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone as applied to claim 1, and further in view of Lenker et al. (U.S. Patent No. 6,350,278). Applicants respectfully traverse the rejection.

Applicants assert the combination of Stone and Lenker does not disclose every feature of claim 30. Claim 30 depends from claim 1 and is allowable over Stone for at least the same reasons as discussed above with respect to claim 1. Lenker does not overcome the shortcomings of Stone. Lenker also fails to disclose or suggest a rotatable sheath including a first portion arranged axially adjacent a second portion.

For at least these reasons, Stone would not lead a person having skill in the art to the invention of claim 30, even in view of Lenker. Withdrawal of the rejection and allowance of claim 30 is respectfully requested. Applicants do not otherwise concede the correctness of the rejection and reserve the right to make additional arguments if necessary.

Claims 31, 32, and 34 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone as applied to claim 1, and further in view of the Noveon reference ([www.estane.com](http://www.estane.com)). Applicants respectfully traverse the rejection.

Applicants assert the combination of Stone and Noveon does not disclose every feature of claims 31, 32, and 34. Claims 31, 32, and 34 depend from claim 1 and are allowable over Stone for at least the same reasons as discussed above with respect to claim 1. Noveon does not overcome the shortcomings of Stone. Noveon also fails to disclose or suggest a rotatable sheath including a first portion arranged axially adjacent a second portion. Rather, the Noveon reference discloses thermoplastic polyurethane resins for use in medical procedures.

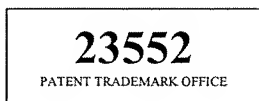
For at least these reasons, Stone would not lead a person having skill in the art to the invention of claims 31, 32, and 34, even in view of Noveon. Withdrawal of the rejection and allowance of claims 31, 32, and 34 is respectfully requested. Applicants do not otherwise concede the correctness of the rejection and reserve the right to make additional arguments if necessary.

Claim 36 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone as applied to claim 35, and further in view of the Noveon reference. Applicants respectfully traverse the rejection.

Claim 36 depends from claim 1 and is allowable over the combination of Stone and the Noveon reference for at least the same reasons as discussed above with respect to claims 31, 32, and 34. For at least these reasons, Stone would not lead a person having skill in the art to the invention of claim 36, even in view of Noveon. Withdrawal of the rejection and allowance of claim 36 is respectfully requested. Applicants do not otherwise concede the correctness of the rejection and reserve the right to make additional arguments if necessary.

### Conclusion

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.



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Respectfully submitted,

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